

**REMARKS**

Initially, Applicants thank the Examiner for indicating that there are no art-based rejections of the claims and that claims 10 and 11 would be allowable in independent form. Further, as discussed herein, Applicants respectfully request reconsideration and withdrawal of the rejections of record.

***Status of the Claims***

Claims 1-9 and 12-14 were pending and stand rejected. Claims 10 and 11 are objected to as depending from a rejected claim. Claims 1-14 are now canceled without prejudice or disclaimer. New claims 15-35 are presented.

***Response to Formal Objections***

Claim 2 is objected to as allegedly being a substantial duplicate of claim 1. The objection is believed to be moot in view of the new claims.

Claims 8 and 9 are objected to as containing improper dependency. The objection is believed to be moot in view of the new claims, which avoid multiply dependent claims depending from multiply dependent claims.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the objections.

***Response to Indefiniteness Rejection***

Claims 1-9 and 12-14 are rejected under 35 USC § 112, ¶ 2, as allegedly being indefinite.

In order to expedite prosecution, Applicants have amended the recitation of R<sup>3</sup> to specify the definite range of 1 to 4 substituents. Applicants note that the examples provided in the specification contain 1 to 4 R<sup>3</sup> substituents. For instance, see Example 17. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Applicants note that it is settled law that claim breadth is not to be equated with indefiniteness. Thus, one having ordinary skill in the art would have understood the scope of that recitation to mean at least one and without an upper boundary except as dictated by the chemistry of a given compound as would be understood by such skilled artisan. This would include up to twenty-one substituents chemically permitting, as would be understood by the skilled artisan, and as generally recognized in the rejection. Accordingly, Applicants respectfully submit that the rejection is not supported in this case.

***Response to Written Description Rejection***

Claim 13 is rejected under 35 USC § 112, ¶ 1, as allegedly failing to comply with the written description requirement. The rejection states that the claim reaches out to as-yet undiscovered diseases.

In order to expedite prosecution, claim 13 has been canceled without prejudice or disclaimer and replaced with claims 34 and 35. Thus, the rejection is believed to be moot. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants note that claim 13 is an original claim. Thus, there is no lack of written description in the traditional sense because the disclosure per se includes a description of the claimed subject matter. There is also no lack of written description in the sense of the requirement as applied in cases such as Univ. California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997) or in the USPTO Examination Guidelines, which have been adopted by the Federal Circuit. This aspect of the law merely requires that the claimed subject matter be described in terms of some structure in combination with function. In contrast to a hypothetical method claim that may recite *any* "5-HT<sub>4</sub> agonist or antagonist" without regard to structure, claim 13 specifies a definite genus of chemical subject matter. Moreover, the recitation of treating conditions "mediated by 5-HT<sub>4</sub>" with the compounds provides a direct technical link between the compounds and their activity disclosed in the specification. Thus, the skilled artisan would recognize that Applicants were in possession of the compounds themselves and their use against diseases mediated by 5-HT<sub>4</sub>. Even more than a claim reciting a named disease, claim 13 specifies only conditions mediated by the receptor for which the compounds are known to be active. Thus, Applicants have provided structure and a relationship between structure and function as required by § 112, ¶ 1.

***Response to Enablement Rejection***

Claims 1-9 and 12-14 are rejected under 35 USC § 112, ¶ 1, as allegedly lacking enablement. The composition and method claims are treated separately below.

**Composition Claims**

Claims 1-9 and 12 are rejected. The rejection states (p. 4) that the specification is enabling only for the species examples recited in claims 10 and 11 and the compounds wherein R<sup>3</sup> is substituted by two substituents, and heterocyclic being an unsaturated monocyclic group. The rejection also states (p. 5) that the specification examples are limited to wherein the R<sup>3</sup> group has one or two substituents and wherein the heterocyclic substituent is piperidinyl, morpholinyl, or tetrahydropyranyl, and that no example containing twenty-one R<sup>3</sup> substituents is given in the specification.

The rejection refers only to the examples but does not explain *why* the specification

as a whole allegedly would not enable the skilled artisan to prepare the claimed compounds. All of the statements in the rejection regarding alleged unpredictability relate to the use of the compounds, not the compounds per se. Thus, the rejection does not satisfy the basic burden on the Patent Office to establish a lack of enablement of the claimed compounds and compositions. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 369 (CCPA 1971).

Applicant is entitled to claim more broadly than the specific examples, and enablement is not defeated simply because some experimentation may in some cases be required to produce a claimed material. *In re Wands*, 858 F.2d 731, 736-37, 8 USPQ2d 1400 (Fed. Cir. 1988).

In fact, the specification is enabling of the claims. In this connection, Applicants first notes that new claims 15-32 recite chemical compounds and compositions thereof having, *inter alia*, 1 to 4 substituents on the R<sup>3</sup> alkyl group. The specification teaches, e.g., in Scheme 1, the coupling of an amine compound (IV) which includes R<sup>3</sup>. Scheme 8 describes methods of preparing an R<sup>3</sup>-substituted methyl amino piperidine. The epoxide reagent disclosed may have diverse substituents. Alternatively, the specification discloses that compound (I) may be prepared by treating compound (XVIII) with an alkyl halide containing R<sup>3</sup>. See, e.g., Scheme 7; see also Scheme 10. Obviously, innumerable alkyl and acid halides and multi-substituted alkyl and acid halides are known in the art, commercially available, or could be made by the ordinarily skilled artisan in order to produce the compounds of the claims. Thus, the claimed compounds may be prepared in view of the specification without undue experimentation. Of course, the dependent claims are still more clearly enabled. The rejection gives no reason why the chemistry required to introduce an R<sup>3</sup> group having 1 to 4 specified substituents is not enabled.

In view of the above, reconsideration and withdrawal of the rejection are respectfully requested.

#### Method of Use Claims

Claims 13 and 14 are rejected. The rejection states that the 5-HT receptor ligand art is recognized as unpredictable and that slight change in structure would drastically alter affinity and selectivity. The rejection further states that no results are shown and that no *in vivo* procedures are described.

Applicants believe that the rejection is moot in view of new claims 34 and 35, which recite, respectively, agonizing or antagonizing 5-HT<sub>4</sub> in a subject, but are not limited to attaining treatment or prevention of specific diseases. The specification discloses that the claimed compounds are 5-HT<sub>4</sub> binders or modulators, which could easily be tested by the

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skilled artisan for individual compounds. Routine screening is not undue experimentation. Wands, supra. Thus, the assertions in the rejection regarding certain diseases are not believed to pertain to the new claims. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In addition, Applicants respectfully traverse the assertions and conclusions in the rejection. First, the specification does disclose the use of the claimed compound to treat disease, including dosage levels, and modes of administration, i.e., *in vivo* procedures. See, e.g., pp. 36-37. Here too, the rejection appears to impose an improper requirement that the examples disclose the full scope of the claims. Methods for assessing the activity of the compounds are also disclosed. The skilled artisan could thereby use the claimed compounds without undue experimentation. The rejection also asserts that the precise role of 5-HT<sub>4</sub> is not agreed upon. Regardless, the skilled artisan could prepare and routinely test the claimed compounds to determine its specific properties within the claimed genus. Thus, Applicants respectfully traverse the rejection.

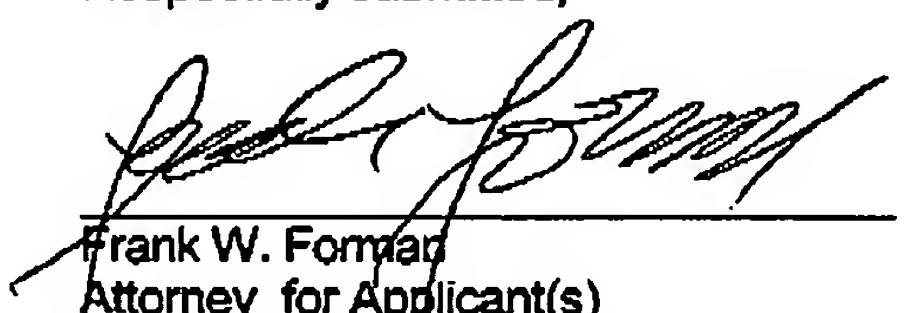
#### Conclusion

In view of the above, Applicants respectfully submit that all of the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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